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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts, December, 1999

Dear Sirs:

This letter is written in response to above-captioned draft guidance and offers comments, criticisms and alternatives.

I share the FDA's concern that xenotransplantation may inadvertently introduce zoonoses into the human population. Despite the health benefit that xenotransplantation may someday provide, even research in this area must be approached cautiously. Therefore, consideration of further transmission of zoonoses to other humans through transfusion is an appropriate topic for FDA guidance.

The mechanism proposed by FDA in this draft guidance, however, is entirely unrealistic and inappropriate for the level of risk that xenotransplantation conveys.

To begin, I would point out that the current health history questionnaire is already lengthy. At my last count, it exceeds 38 detailed questions and has earned the sobriquets of "interrogation" and "inquisition". When blood collection agencies must depend on the largesse of individuals and companies who are increasingly pressed for time, it is not happenstance, I believe, that lengthening of the questionnaire over the last few years has been associated with further reductions in donation frequency and increasing difficulties in scheduling mobile blood drives at places of employment. At a time when other sectors of HHS, and of the FDA, are directing attention to increasing donation rates, any new impediment to donation should be directed toward an identifiable safety risk and be proportionate in impact to that risk. The provisions of the draft guidance fail these tests.

The concepts embodied in the guidance are not unreasonable safety measures, but their implementation should be streamlined to reflect the lack of identified risk at this point and the minuscule volume of xenotransplantation occurring at present. A simpler alternative that would accomplish the bulk of the safety increment might be as follows: Question prospective donors whether they have ever received a transplant or injection of human or animal tissue. This question could replace ones currently used for dura mater transplants, thus gaining the most important information without lengthening the "interrogation". The other direct questions proposed in the draft guidance should then be omitted but their deferral guidelines be (1) mentioned in the educational information provided to prospective donors, and (2) included in the blood collection agency's SOP as deferral criteria. This approach would provide the same level of safety - against a theoretical risk - without prolonging an already lengthy process of donor qualification, engendering innumerable blank stares of noncomprehension from confused donors, and yielding few if any true-positive responses.

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Furthermore, I would recommend that a similar approach be adopted for percutaneous exposures of healthcare workers. A single, generic question about needlestick injury could be asked; the details of deferral based on the timing, kind and source of exposure could be imbedded in the collection agency's SOP for reference as appropriate.

Questioning prospective donors about the potential exposures of others in the household or of their sexual partners will be fruitless. Given the low volume of (research) procedures currently employing xenotransplantation, the potential *even for exposure* is minute, let alone that of transmission. Given the problems donors have knowing the sexual and drug-use exposures of their sexual partners, expecting them to know of zoonotic exposures of their partners is doomed to failure and hilarity.

I urge the FDA to adopt reasonable, practical guidelines regarding potential zoonotic risks.

Sincerely,

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